#15 YC 4-22-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	Simon F. Williams and David P. Martin		
Serial No.:	09/661,773	Group Art Unit:	1615
Filed:	September 14, 2000	Examiner:	C. A. Azpuru

For: *POLYHYDROXYALKANOATE COMPOSITIONS FOR SOFT TISSUE REPAIR, AUGMENTATION AND VISCOSUPPLEMENTATION*

Assistant Commissioner for Patents
Washington, D.C. 20231

APPEAL BRIEF

Sir:

This is an appeal of the final rejection of claims 1-17 and 29-32 in the Office Action mailed September 18, 2002, maintained in the Advisory Action mailed January 15, 2003, in the above-identified patent application. A Notice of Appeal was mailed on January 21, 2003. A check in the amount of $160.00 for the filing of this Appeal Brief by a small entity is also enclosed. Submitted with this Appeal Brief is a Petition for Extension of Time, along with the required $55.00 fee for a small entity, to extend the period for filing appeal brief one month, to and including April 21, 2003.

(1) REAL PARTY IN INTEREST

The real party in interest of this application is the assignee, Tepha, Inc.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellant, the undersigned, or appellant's assignee which directly affects, which would be directly affected by, or which would have a bearing on the Board's decision in this appeal.

(3) STATUS OF CLAIMS ON APPEAL

Claims 1-17 and 29-32 are pending. Claims 11-17 and 29-32 are on appeal. The text of each claim on appeal, as amended, is set forth in the Appendix to this Appeal Brief.

(4) STATUS OF AMENDMENTS

The claims were amended in the Amendment mailed July 25, 2002.

(5) SUMMARY OF THE INVENTION

The appellants have designed and made various biocompatible polyhydroxyalkanoate ("PHA") materials suitable for repair of soft tissue, augmentation, and as viscosupplements in animals, particularly humans (p. 3, lines 22-24). In a preferred embodiment, these materials contains liquid polyhydroxyalkanoate polymer compositions or polyhydroxyalkanoate microdispersions having low viscosities which enable the materials to be injected into soft tissue or the knee joint with a syringe and needle (p. 3, lines 24-26). These polymers can be made not to harden after implantation (p. 3, lines 26-27). Degradation rates of the materials can be

controlled so that certain compositions are slow to bioabsorb, thereby decreasing considerably the frequency with which the composition must be re-injected (p. 3, lines 27-29). These critical aspects solve a long-felt but unsolved need in the art. A variety of different materials have been used to repair or augment soft tissue defects or to contour abnormalities caused by facial defects, acne, surgical scarring, trauma or aging. However, those materials have a variety of shortcomings, e.g., migration to distant parts of the body to cause physiological and clinical problems by silicone based materials, rapid absorption by tissue of bovine collagen, rapid degradation of the materials, rapid diffusion out of the site of implantation, or undesirable physical and mechanical properties (see p. 1, line 11 to p. 2, line 29). The compositions described and defined in the present application solved the problems associated with those materials (see p. 14, line 1 to p. 18, top, Examples 1-6).

The fluid compositions may contain PHA liquid copolymer, which can be used alone or blended with other PHA polymers or other suitable materials prior to use (p. 8, lines 25-29), which is made by decreasing the molecular weight of the polymer or varying the viscosity of the liquid PHA polymers (p. 3, lines 22-29). The viscosity of the liquid PHA polymers can be varied by changing the molecular weight of the polymer, crosslinking, and/or by changing the composition of the polymers (p. 9, lines 13-15). A suitable viscosity would allow manual injection of the fluid defined in the claims through a 16 gauge needle or smaller gauge needle (p. 10, lines 3-5). A suitable range of viscosity would be less than about 1,00,000 cp, preferably in the range from that of water (1 cP) to about that of molasses (100,000 cP) (p. 10, lines 5-7). Suitable methods for decreasing the molecular weight of PHA polymers, particularly to convert

them from solid to liquid forms, include hydrolysis, enzymatic degradation, irradiation, and mechanical or thermal treatments (p. 9, lines 17-20). The fluid composition may also contain a microdispersion of microparticulate PHA polymer in a fluid carrier. The PHA particulates have a diameter less than about 500 μm, preferably less than 50 μm, and most preferably less than about 5 μm (p. 10, lines 26-29). Suitable fluid carriers include liquid PHA polymers and aqueous solutions (p. 10, lines 26-27).

The compositions may also include other agents such as compounds with ani-microbial activity, anesthetics, adjuvants, anti-inflammatory compounds, surfactants, steroids, lipids, enzymes, antibodies, hormones, pharmacologically active or bioactive compounds, and dyes, proteins, and peptides (p. 11, lines 20-27).

The compositions are useful for a variety of soft tissue repair and augmentation procedures, and as viscosupplements as described at p. 12, lines 8-16 and lines 18-20.

(6) ISSUES ON APPEAL

The issue presented on appeal are

(1) whether claims 1-17 and 29-32 are anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,277,413 to Sankaram ("Sankaram").

(7) GROUPING OF CLAIMS

The claims do not stand or fall together, as discussed below in detail. While claims 2-17 depend on claim 1, prior art generally relating to the composition of claim 1 does not disclose the

composition of any of claims 2-17. Claim 2 require the composition of claim 1 to be liquid or wax at a temperature between about 20 and 25 °C. Claims 3-4 require the composition of claim 1 to be liquid at the body temperature of an animal or 37 °C. Therefore, prior art allegedly relating to claim 1 does not disclose any of the additional features in each of claims 2-4.

Claim 5 requires biocompatible fluid in the composition of claim 1 to be a microdispersion of particles of a PHA polymer dispersed in a physiologically compatible liquid carrier. Claim 6 further requires the carrier in the composition of claim 5 to be a second PHA or an aqueous solution. Each of claims 7-9 further defines the microparticles of claim 5 to have a diameter of less than about 500 μm, less than about μm, or less than 5 μm, respectively. Therefore, prior art allegedly relating to claim 1 does not disclose any of the additional features in each of claims 5-9.

Claim 10 requires the PHA polymer in the composition of claim 1 to be specifically derived from one or more monomers listed therein. Therefore, prior art allegedly relating to claim 1 does not disclose the polymer of claim 10.

Claims 11 and 12 specifically require the molecular weight of the PHA polymer in the composition of claim 1 to be less than 100,000 or less than 50,000 as determined by gel permeation chromatography. As such, prior art allegedly relating to claim 1 does not disclose any of the additional features in each of claims 11-12.

Claim 13 and 14 further require the viscosity of the composition of claim 1 to be between about 1 and 100,000 cP or between about 1 and 10,000 cP, respectively. Therefore, prior art allegedly relating to claim 1 does not disclose any of the additional features in each of claims 13-

14.

Claim 15 requires the composition of claim 1 to further include a bioactive agent. Claim 16 requires the composition of claim 1 to further include a peptide or protein. Claim 17 requires the PHA in the composition of claim 1 to be a peptide or protein. Therefore, prior art allegedly relating to claim 1 does not disclose any of the additional features in each of claims 15-17.

Claim 29 defines a composition suitable for use in the treatment of osteoarthritic knees in which the composition defined in claim 29 is used as viscosupplements. Claim 30 further requires the PHA in the composition of claim 29 to be amorphous. Therefore, prior art allegedly relating to claim 29 does not disclose this additional feature of claim 30.

Claim 30 defines a kit including the composition of claim 1 and a means for delivering the composition to a patient. Claim 32 further requires the means for delivering in the kit of claim 31 to include a needle and a syringe. Therefore, prior art allegedly relating to claim 31 does not disclose any of the additional features in claim 32.

(8) ARGUMENTS

(a) The Claimed Method Solves A Long-Felt but Unsolved Need and Produces Better Results than the Prior Art

Claim 1 is drawn to a composition for the repair or augmentation of tissue in an animal or human. The composition contains a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate which is injectable into a human or animal for repair or augmentation of tissue. Claim 29 is drawn to a composition useful for in the treatment of osteoarthritic knees.

The composition contains a biocompatible, bioabsorbable fluid which comprises a PHA, wherein the composition is suitable for use as a viscosupplements. Claim 31 is dawn to a kit having the composition of claim 1 and a means for delivering the composition to a patient.

The dependent claims add further limitations:

The composition of claim 1 is further limited to a composition which is a liquid or wax at a temperature between 20 and 25 °C (claim 2), which is a liquid at the body temperature of an animal (claim 3), or which is a liquid at about 37 °C (claim 4). The composition of claim 1 is further limited to a microdispersion of particles dispersed in a physiologically compatible liquid carrier (claim 5) which may be a second PHA polymer or an aqueous solution (claim 6). The particles of claim 5 can have a diameter of less than about 500 μm (claim 7), less than about 50 μm (claim 8), or less than about 5 μm (claim 9). The composition of claim 1 is also limited by specific monomers from which the PHA polymer in composition of claim 1 is derived (claim 10), by specifically requiring the molecular weight of the PHA polymer to be less than 100,000 (claim 11) or less than 50,000 (claim 12), by requiring the viscosity of the composition to be between 1 and 100,000 cP (claim 13) or between 1 and 10,000 cP (claim 14), or by requiring the PHA polymer to be amorphous (claim 17). The composition of claim 1 may additionally contain a bioactive agent (claim 15) or a protein or peptide (claim 16).

The composition of claim 29 is further limited by requiring the PHA polymer of claim 29 to be amorphous (claim 30).

The kit of claim 31 is further limited by requiring the means for delivering to include a needle and a syringe (claim 32).

There is a great need for materials useful in soft tissue repair and augmentation and as viscosupplements. Prior to the development of the compositions disclosed in the present application, quite a few materials have been designed and made (see, for example, U.S. Patent Nos. 5,204,382; 4,235,312; 5,728,752; 5,709,854 and 5,824,333, and PCT/US96/09065). Unfortunately, all of these materials have shortcomings which limit the effectiveness or efficacy of their use in soft tissue repair and augmentation or as viscosupplements. These materials migrate to distant parts of the body receiving the materials, harden upon administration, rapidly degrade, diffuse out of the site of implantation, or are undesirably rapidly absorbed or nonabsorbable (p. 1, line 6 to p. 2, line 29).

The appellants have solved the long-felt, but unsolved need. The appellants found that via manipulation of several factors one can modulate the properties of PHA compositions so as to render them suitable for use in soft tissue repair and/or as viscosupplements (p. 3, lines 20-23). In particular, the appellants achieved the desirable result using a fluid composition which may be a liquid PHA polymer composition or a microdispersion of particulate PHA polymer dispersed in a liquid carrier or an aqueous solution (p. 3, lines 9-10). The fluid composition can be formed by lowering the molecular weight of high molecular weight PHA polymers to less than 100,000, preferably less than 50,000 (p. 9, lines 21-22), varying the viscosity of the PHA polymer used such that the viscosity of the PHA polymer is less than 1,000,000, preferably in the range between, for example, 1 to 100,000 cP (p. 10, lines 5-7). Suitable methods for decreasing the molecular weight of PHA polymers, particularly to convert them from solid to liquid forms, include hydrolysis, enzymatic degradation, irradiation, and mechanical or thermal treatments (p.

9, lines 17-20). Suitable viscosity of the liquid PHA polymers can be achieved by changing the molecular weight of the polymer, crosslinking, and/or by changing the composition of the polymers (p. 9, lines 13-15). A suitable viscosity would allow manual injection of the fluid defined in the claims through a 16 gauge needle or smaller gauge needle (p. 10, lines 3-5). A suitable range of viscosity would be less than about 1,00,000 cp, preferably in the range from that of water (1 cP) to about that of molasses (100,000 cP) (p. 10, lines 5-7).

The fluid composition may also contain a microdispersion of microparticulate PHA polymer in a fluid carrier. The PHA particulates have a diameter less than about 500 μm, preferably less than 50 μm, and most preferably less than about 5 μm (p. 10, lines 26-29). Suitable fluid carriers include liquid PHA polymers and aqueous solutions (p. 10, lines 26-27). The compositions may also include other agents such as compounds with ani-microbial activity, anesthetics, adjuvants, anti-inflammatory compounds, surfactants, steroids, lipids, enzymes, antibodies, hormones, pharmacologically active or bioactive compounds, and dyes, proteins, and peptides (p. 11, lines 20-27).

The appellants found that The compositions are useful for a variety of soft tissue repair and augmentation procedures, and as viscosupplements. Exemplary applications include, for example, camouflaging scars, filling depressions, smoothing out irregularities, correcting asymmetry in facial hemiatrophy, second branchial arch syndrome, facial lipodystrophy and camouflaging age-related wrinkles as well as augmenting facial eminences (lips, brows, etc.) (p. 12, lines 8-14). Additionally, these compositions can be used to restore or improve sphincter function such as for treating stress urinary incontinence (p. 12, lines 14-16). Other uses include

the treatment of vesicoureteral reflux by subureteric injection and application of these materials as general purpose fillers in the human body (p. 12, lines 18-20).

Examples 1-6 demonstrate the making of an injectable fluid PHA composition defined in claim 1.

As discussed below, the prior art reference provides no guidance to form a fluid PHA compositions which possesses desirable chemical, physical, and mechanical properties for use in soft-tissue repair and augmentation and as viscosupplements. Therefore the prior art not only fails to disclose or make obvious the subject matter of the independent claims, but also fails to disclose or make obvious the subject matter of the dependent claims.

(b) Rejections under 35 U.S.C. §102(e)

Claims 1-17 and 29-32 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,277,413 to Sankaram ("Sankaram").

1. The cited art

Sankaram

Sankaram is drawn to a pharmaceutical composition having microspheres which include both polymer and **lipid** components for use in drug delivery (col. 2, line 67 to col. 3, line 1; col. 8, line 57 to col. 9, line 35). The ratio of lipid to polymer varies from 20:1 to about 1:5, preferably 19:1 to about 1:3 (col. 10, lines 51-53). Polyhydroxyalkanoate (PHA) can be used to make the microspheres (col. 3, line 17). There is no disclosure of a composition containing PHA that imparts to the fluid composition properties so as to make it suitable for the repair or

augmentation of tissue in an animal or human, as claimed.

2. The Legal standard under 35 U.S.C. § 102

In making an anticipation rejection under 35 U.S.C. § 102, the examiner has to ascertain that each and every element of a claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The examiner must show that the identical subject matter is disclosed in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Moreover, the elements disclosed in a reference must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

3. Claims 1-17 and 29-32 are not anticipated by Sankaram

As discussed above, Sankaram discloses a pharmaceutical composition rather than a composition suitable for use in soft tissue repair and augmentation and as viscosupplements. To be suitable for use in soft tissue repair and augmentation or as viscosupplements, a material is required to have a certain set of chemical, physical, mechanical, and biological properties (see p. 1 to p. 2 of the present application). The appellants designed and made a composition which is a fluid suitable for tissue repair or augmentation or use as a viscosupplements because the composition possesses desirable physical properties, e.g., viscoelasticity, elasticity, pulpability, or flexibility, and chemical and biological properties which are critical attributes of PHA compositions having a certain type of PHA polymer of certain molecular weight in certain formulations (see, e.g., p. 8, line 24 to p. 11, line 19 of the present application). Sankaram does

not teach or suggest these critical features of a composition suitable for use in soft tissue repair and augmentation or as viscosupplements. Therefore, Sankaram does not disclose claims 1-17 and 29-32.

Further, as described in Sankaram at col. 10, lines 50-53, a substantial part (20% to 100%) of the composition described therein is lipid. To one of ordinary skill in the art, lipid undergoes rapid metabolism upon administration to a patient and is rapidly absorbed (see Weinstock, et al., J Lipid Res 38 (9): 1782-1794 (1997)). As discussed at p. 1 to p. 2 of the present application, it is not desirable that materials to be used in soft tissue repair and augmentation and as viscosupplements to be metabolized or absorbed rapidly by the body of an animal. Therefore, the fact that Sankaram requires the composition described therein to have a substantial percentage of lipid further demonstrates that the composition of Sankaram is not suitable for use in soft-tissue repair and construction and as viscosupplements.

In summary, Sankaram does not anticipate claims 1-17 and 29-32 under 35 U.S.C. § 102. *See Richardson*, 868 F.2d at 1236, 9 USPQ2d at 1920; *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566.

4. Claims 1-17 and 29-32 as amended are not anticipated by Sankaram

The proposed amendment to claims 1-17 and 29-32 further clarifies that the composition defined in any of claims 1-17 is a bulking agent and the composition defined in any of claims 29-30 is a viscosupplement. The original claim 1 provides that the composition is suitable for use in soft tissue repair and augmentation. The original claim 29 provides that the composition defined therein is suitable for use as viscosupplements. Therefore, the proposed amendment to the

claims does not introduce any new matter.

As the foregoing discussion shows, Sankaram fails to teach or suggest a composition which is a bulking agent or a viscosupplement. Therefore, Sankaram does not anticipate claims 1-17 and 29-32, as amended, under 35 U.S.C. 102(e).

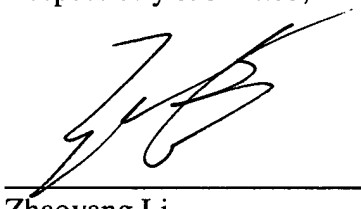
(9) SUMMARY

The prior art fails to disclose the claimed composition and kit.

(10) CONCLUSION

Allowance of all claims 1-17 and 29-32 is earnestly solicited.

Respectfully submitted,



Zhaoyang Li
Reg. No. 46,872

Date: April 7, 2003
Holland & Knight LLP
One Atlantic Center, Suite 2000
1201 West Peachtree Street
Atlanta, GA 30309-3400
(404) 817 – 8473
(404) 817 – 8588 (fax)

Certificate of Mailing Under 37 CFR § 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to United States Patent and Trademark Office, P. O. Box 2327, Arlington, Va. 22202.

Peggy Bailey

Peggy Bailey

Date: April 7, 2003

TABLE OF CONTENTS

Appendix I: Claims on Appeal

1. (amended) A composition for the repair or augmentation of tissue in an animal or human, comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate which is injectable into a human or animal for repair or augmentation of tissue.

2. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid or wax at a temperature between about 20 and 25 °C.

3. The composition of claim 1 wherein the polyhydroxyalkanoate is liquid at the body temperature of the animal.

4. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid at about 37 °C.

5. The composition of claim 1 wherein the biocompatible fluid is a microdispersion of particles of the polyhydroxyalkanoate dispersed in a physiologically compatible liquid carrier.

6. The composition of claim 5 wherein the carrier is a second polyhydroxyalkanoate or an aqueous solution.

7. (amended) The composition of claim 5 wherein the particles have a diameter of less than about 500 μm.

8. The composition of claim 7 wherein the diameter is less than about 50 μm.

9. The composition of claim 8 wherein the diameter is less than about 5 μm.

10. The composition of claim 1 wherein the polymer is derived from one or more monomers selected from the group consisting of 2-hydroxybutanoate, 3-hydroxyalkanoates, 3-hydroxyalkenoates, 4-hydroxyalkanoates, 4-hydroxyalkenoates, 5-hydroxyalkanoates, 5-

hydroxyalkenoates, 6-hydroxyalkanoates, and 6-hydroxyalkenoates.

11. (amended) The composition of claim 1 wherein the polyhydroxyalkanoate has a molecular weight of less than 100,000 as determined by gel permeation chromatography.

12. (amended) The composition of claim 11 wherein the molecular weight is less than 50,000 as determined by gel permeation chromatography.

13. The composition of claim 1 having a viscosity between about 1 and 100,000 cP.

14. The composition of claim 13 having a viscosity between about 1 and 10,000 cP.

15. (amended) The composition of claim 1 further comprising a bioactive agent.

16. The composition of claim 1 further comprising a peptide or protein.

17. The composition of claim 1 wherein the polyhydroxyalkanoate is amorphous.

29. (amended) A composition suitable for use in the treatment of osteoarthritic knees comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate, wherein the composition is suitable for use as a viscosupplement.

30. The composition of claim 28 wherein the polyhydroxyalkanoate is amorphous.

31. (amended) A kit comprising

(a) the composition of claim 1; and

(b) a means for delivering the composition to a patient.

32. The kit of claim 31 wherein the means for delivering comprises a needle and a syringe.

Appendix II: Marked-up Claims on Appeal as Amended

1. (Twice amended) A composition for the repair or augmentation of tissue in an animal or human, comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate which is injectable into a human or animal for repair or augmentation of tissue,

wherein the composition is a bulking agent.

2. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid or wax at a temperature between about 20 and 25 °C.

3. The composition of claim 1 wherein the polyhydroxyalkanoate is liquid at the body temperature of the animal.

4. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid at about 37 °C.

5. The composition of claim 1 wherein the biocompatible fluid is a microdispersion of particles of the polyhydroxyalkanoate dispersed in a physiologically compatible liquid carrier.

6. The composition of claim 5 wherein the carrier is a second polyhydroxyalkanoate or an aqueous solution.

7. (amended) The composition of claim 5 wherein the particles have a diameter of less than about 500 μm.

8. The composition of claim 7 wherein the diameter is less than about 50 μm.

9. The composition of claim 8 wherein the diameter is less than about 5 μm.

10. The composition of claim 1 wherein the polymer is derived from one or more monomers selected from the group consisting of 2-hydroxybutanoate, 3-hydroxyalkanoates, 3-

hydroxyalkenoates, 4-hydroxyalkanoates, 4-hydroxyalkenoates, 5-hydroxyalkanoates, 5-hydroxyalkenoates, 6-hydroxyalkanoates, and 6-hydroxyalkenoates.

11. (amended) The composition of claim 1 wherein the polyhydroxyalkanoate has a molecular weight of less than 100,000 as determined by gel permeation chromatography.

12. (amended) The composition of claim 11 wherein the molecular weight is less than 50,000 as determined by gel permeation chromatography.

13. The composition of claim 1 having a viscosity between about 1 and 100,000 cP.

14. The composition of claim 13 having a viscosity between about 1 and 10,000 cP.

15. (amended) The composition of claim 1 further comprising a bioactive agent.

16. The composition of claim 1 further comprising a peptide or protein.

17. The composition of claim 1 wherein the polyhydroxyalkanoate is amorphous.

29. (Twice amended) A composition suitable for use in the treatment of osteoarthritic knees comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate, wherein the composition is suitable for use as a viscosupplement,

wherein the composition is a viscosupplement.

30. The composition of claim 28 wherein the polyhydroxyalkanoate is amorphous.

31. (amended) A kit comprising

(a) the composition of claim 1; and

(b) a means for delivering the composition to a patient.

32. The kit of claim 31 wherein the means for delivering comprises a needle and a syringe.

Appendix III: Clean version of Claims on Appeal as Amended

1. (Twice amended) A composition for the repair or augmentation of tissue in an animal or human, comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate which is injectable into a human or animal for repair or augmentation of tissue,

wherein the composition is a bulking agent.

2. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid or wax at a temperature between about 20 and 25 °C.

3. The composition of claim 1 wherein the polyhydroxyalkanoate is liquid at the body temperature of the animal.

4. The composition of claim 1 wherein the polyhydroxyalkanoate is a liquid at about 37 °C.

5. The composition of claim 1 wherein the biocompatible fluid is a microdispersion of particles of the polyhydroxyalkanoate dispersed in a physiologically compatible liquid carrier.

6. The composition of claim 5 wherein the carrier is a second polyhydroxyalkanoate or an aqueous solution.

7. (amended) The composition of claim 5 wherein the particles have a diameter of less than about 500 μm.

8. The composition of claim 7 wherein the diameter is less than about 50 μm.

9. The composition of claim 8 wherein the diameter is less than about 5 μm.

10. The composition of claim 1 wherein the polymer is derived from one or more monomers selected from the group consisting of 2-hydroxybutanoate, 3-hydroxyalkanoates, 3-

hydroxyalkenoates, 4-hydroxyalkanoates, 4-hydroxyalkenoates, 5-hydroxyalkanoates, 5-hydroxyalkenoates, 6-hydroxyalkanoates, and 6-hydroxyalkenoates.

11. (amended) The composition of claim 1 wherein the polyhydroxyalkanoate has a molecular weight of less than 100,000 as determined by gel permeation chromatography.

12. (amended) The composition of claim 11 wherein the molecular weight is less than 50,000 as determined by gel permeation chromatography.

13. The composition of claim 1 having a viscosity between about 1 and 100,000 cP.

14. The composition of claim 13 having a viscosity between about 1 and 10,000 cP.

15. (amended) The composition of claim 1 further comprising a bioactive agent.

16. The composition of claim 1 further comprising a peptide or protein.

17. The composition of claim 1 wherein the polyhydroxyalkanoate is amorphous.

29. (Twice amended) A composition suitable for use in the treatment of osteoarthritic knees comprising

a biocompatible, bioabsorbable fluid which comprises a polyhydroxyalkanoate, wherein the composition is suitable for use as a viscosupplement,

wherein the composition is a viscosupplement.

30. The composition of claim 28 wherein the polyhydroxyalkanoate is amorphous.

31. (amended) A kit comprising

(a) the composition of claim 1; and

(b) a means for delivering the composition to a patient.

32. The kit of claim 31 wherein the means for delivering comprises a needle and a syringe.